AMENDMENT TO SPECIFICATION

Please amend the following paragraphs and Abstract:

[0008] In one embodiment, the sensor device may include a sensor element configured to monitor in vivo a physiological parameter associated with a patient and a plurality of ~~imagable~~ imageable marker properties.

[0013] Figure 1A illustrates an enlarged imaged ~~prostrate~~ prostate area of patient's body having a sensor device and a plurality of marker seeds.

[0014] Figure 1B illustrates an enlarged imaged prostate area using a second imaging modality having an array of markers that are ~~imagable~~ imageable and a sensor device that is not ~~imagable~~imageable.

[0040] In one embodiment, the target may be a sensor device. Although, the following discussion may be in reference to a sensor device, the sensor device may also have telemetric capabilities such as a responder or a transponder. In one embodiment, the method and apparatus described provides a means to localize in the body one or more sensor devices (e.g., sensor, responder, transponder, etc.). The sensor device may be situated in the body through various means, for example, implantation through injection. The site may be, for examples, adjacent a tumor, normal tissue or any other area of interest. The device may be identified by imaging techniques that measure, for examples, radio-opacity, ultrasound, magnetic or other characteristics that may be imaged. The ~~imagable~~ imageable properties of the device may be integral in its construction or may be added to the device in order to make it ~~imagable~~imageable. In one embodiment, the device may be situated in the body as part of an array or constellation of ~~imagable~~ imageable markers. One or more of the ~~imagable~~ imageable markers may also be a sensor device.

[0045] Figure 1A illustrates an enlarged imaged ~~prostrate~~ prostate area of a patient's body having a sensor device and a plurality of markers (e.g., marker seeds). The sensor device 100

and the ~~marker~~ markers 110 are situated in or near an area of interest in body 105. In one embodiment, sensor device 100 may be situated within a volume defined by the array of markers ~~seeds~~ 110 as illustrated in Figure 1A. In an alternative embodiment, sensor device 100 may be situated outside a volume define by the array of markers 110.

[0046] For example, the area of interest may be a target volume in body 105 containing a prostate with a tumor cell population as illustrated in Figure 1A. An array of markers 110 may be implanted near the ~~prostrate~~ prostate with the sensor device 100 situated within a volume defined by the array of markers 110. The sensor device 100 may be situated in the prostate to measure the dose of treatment radiation received. Although, conventional imaging techniques can locate a sensor device, it may be desirable to know the sensor device's precise position in the body 105 and, in particular, relative to other anatomical landmarks. For example, if the sensor device 100 is implanted in the prostate to monitor radiation dose delivered to a ~~prostrate~~ prostate tumor, then the device's proximity to other anatomical landmarks (e.g., the rectal wall) would be desirable to know in order to extrapolate or otherwise determine radiation delivered to these other anatomical landmarks and minimize damage to such areas from subsequent the radiation treatment.

[0047] It should be noted that Figures 1A and 1B illustrate a ~~prostrate~~ prostate area only for ease of discussion and that the invention is not limited to use only in a prostate area. In alternative embodiments, the area of interest may include any other area in the body such as other organs (e.g., liver or lung), a tumor, normal tissue, etc.

[0050] The markers 110 are intended to remain in position relative to the target tissue volume so that an imaging system can detect the markers as discussed below. In one embodiment, for example, the sensor device and/or the markers 110 may be placed in the needle of a biopsy syringe. The needle is injected into a patient's body and the sensor device and/or a marker ~~seed~~ 110 is expelled from the needle into body tissue. Alternatively, other methods may be used to implant the sensor device and/or the markers 110, such as surgically.

[0052] In one embodiment, markers 110 may be marker seeds. Marker seeds may be cylindrical in shape with a length in the approximate range of 3.0 and 6.0 millimeters and a diameter in the approximate range of 0.5 and 3.0 millimeters. In alternative embodiments, the marker seeds may have other shapes (e.g., rectangular, spherical, etc.) and other dimensions. It should be noted that markers 110 are not limited to only markers seeds. Alternatively, other types of marker devices having ~~imagable~~ imageable properties may be utilized as markers 110, for example, surgical clips and orthopedic screws.

[0055] In one particular embodiment, the markers 110 are constructed of a material(s) such that they may be imaged using two or more modalities (by imaging techniques that measure, for examples, radio-opacity, sonic, magnetic or other material characteristics), as illustrated by Figures 1A and 1B. Figure 1B illustrates a sensor device not ~~imagable~~ imageable in a second modality and an array of markers that are ~~imagable~~ imageable in the second modality. In one embodiment, both the markers 110 and the sensor device 100 may be imaged using a first modality as illustrated by enlarged image 190 in Figure 1A. The image of the array of markers 110 may used to establish an internal coordinate system and the position of the sensor device 100 may be identified relative to one or more markers 110 in the established coordinate system, as discussed below in relation to Figure 6.

[0056] In the second modality, the markers 110 may also be imaged as illustrated by enlarged image 195 of Figure 1B, however, the sensor device 100 may not be ~~imagable~~ imageable in this second modality as shown by the absence of sensor device 100 in enlarged image 195 of Figure 1B. In such an embodiment, the ~~senor~~ sensor device 100 may be identified in the previously established coordinate system using image processing software to relate the positions of the array of markers seeds in the second imaging modality with their positions in the first imaging modality. The location in the body 105 of sensor device 100 imaged in the first modality is determined. When the position of the array of markers 110 in the second modality (illustrated by enlarged image 195) is identified in the coordinate system, the location of the sensor device 100 may be then calculated in the internal coordinate system (i.e., relative to one or more markers 110) and displayed with a computing system as discussed below in relation to Figure 4. The localization process is discussed in more detail below in relation to Figure 6.

[0057] As such, even though sensor device 100 cannot be imaged in second modality 195 of Figure 1B, the location of sensor device 100 in body 105 may be known relative to the array of markers 110. This, in turn, can be related to various anatomical landmarks viewable by the imaging modalities. Accordingly, the location of sensor device 100 can also be known relative to anatomical landmarks. Movement of the ~~senor~~ sensor device 100 caused by, for example, motion of the part of the body in which sensor device 100 is situated can also be measured so that location of the device over an integral of time can be directly calculated or mathematically modeled and predicted. Tracking 3D position verses time may be performed as discussed below in relation to Figure 6. In one embodiment, the resulting trajectory of the markers may then be processed using a predictive filter, for example, as discussed in pending U.S. patent application 09/178,383 titled, "METHOD AND SYSTEM FOR PREDICTIVE PHYSIOLOGICAL GATING OF RADIATION THERAPY," which is herein incorporated by reference. Alternatively, other predictive filters known in the art may be used.

[0059] In another embodiment, the array of markers 110 may be used either with or without sensor device 100 to determine the position of an anatomical landmark using a system that can directly image the array of markers 110 but, perhaps, not the anatomical landmark. In such an embodiment, an anatomical landmark (e.g., bone, organ, or other body structure) is imaged with a first imaging modality and its location in body 105 related to the array of markers 110 that are also ~~imagable~~ imageable with the first imaging modality. The imaging system generates an internal coordinate system based on the array of markers seeds 110 and determines the location of the anatomical landmark in the coordinate system. For example, if an ultrasound imaging system is used, then the imaging system can detect the position of the anatomical landmark and the positions of markers 110 using ultrasound techniques. An internal coordinate system may be calculated using the detected markers. Based on the position of the markers 110, the exact position of the anatomical landmark can be calculated relative to the internal coordinate system (e.g., relative to at least one of the markers).

[0060] At a following session, the array of markers 110 may be ~~imagable~~ imageable in a second imaging modality 195 but not the anatomical landmark. However, even though the

anatomical landmark cannot be imaged in second modality, the location of anatomical landmark may still be determined in the coordinate system by its previously determined positional relation to the markers 110. As such, because the markers 110 are ~~imagable~~ imageable in second modality 195 of Figure 1B, the position of the anatomical landmark can be determined based on the established internal coordinate system.

[0066] As previously noted, the markers 200 and/or imaging properties may be disposed in various locations on sensor device 100 and in different patterns on sensor device 100. As such, the orientation of sensor device 100 can be determined through the use of multiple markers 200 of Figures 2A, 2B or multiple imaging property regions (e.g., 310 and 320) of Figure 3. If several ~~senor~~ sensor devices 100 are placed in the body 105, they may each have different marker properties such as through means of multiple imaging markers disposed thereon/therein or multiple imaging properties integral in the sensor device's construction (e.g., part of its casing), thereby making it possible to determine specific device location as well as a device's orientation.

[0067] One or more of ~~senor~~ sensor device 100 and markers 110 may be localized by an image system as illustrated in Figure 4. Figure 4 illustrates one embodiment of a system 400 that represents a treatment planning and/or delivery system. While at times discussed in relation to a treatment planning system, system 400 also represents a treatment delivery system. As such, beam 402 may represent both an imaging beam and a treatment beam depending on the context of the discussion. The planning system and the treatment system may be physically different machines or incorporated together within a machine. In one embodiment, for example, the delivery system may be, for examples, a Clinac® Linear Accelerator and a Multi-Leaf Collimator (MLC™) available from Varian Medical Systems, Inc. of California. The configuration of system 400 shown is only for ease of discussion and illustration purposes and various other configuration known in the art may be used, for example, imager 405 may be located on a gantry rather than incorporated into treatment table 404. It should also be noted that the imaging system 400 may be discussed in relation to particular imaging modalities only for ease of discussion and that other imaging modalities may be used as mentioned above.

[0069] Computer 510 receives the output images of imager ~~406~~ 405 that includes the image of at least one of markers 110, sensor device 100 and/or an anatomical landmark. The images received from imager ~~406~~ 405 are used by computer 510 to develop a coordinate system for markers 110. At a first treatment session using a first imaging modality, markers seeds 110 and a sensor device 100 (and/or an anatomical landmark) are detected and the coordinates for each of the markers 110 are determined and stored in computer 510. Thereafter, at a subsequent session, using a different imaging modality, system 400 can detect the markers 110 and determine their position in the coordinate system by comparison to stored data in computer 510. The position of the sensor device ~~110~~ 100 and/or anatomical landmark not ~~imagable~~ imageable in the second modality may then be determined by computer system 510 through using the previously established coordinate system, as discussed above.

[0081] As previously mentioned, daily treatment machine setup variation and various types of organ movement from that encountered in the treatment planning session contribute to uncertainty in the position of the target volume 403 relative to the treatment machine beam 402 isocenter 401 during a particular treatment session. In order to minimize any such positional offset, markers 110 are used to more closely align target volume 403 with the treatment beam 402. Since the 3D reference coordinates of each marker 110 relative to the planning isocenter 401 was determined in step 630 then, if the markers 110 are ~~imagable~~ imageable during the treatment session, any offset of the markers 110 position with respect to the known beam isocenter at the time of treatment may be determined and corrected.

[0084] In step 660, each marker_110 identified in the second modality image of step 650 is correlated with its 3D reference position as determined in step 620 after projecting the marker from 3D to the 2D image domain based on the known geometry of the acquired image. In one embodiment, the identified markers 110 in step 650 are those that pass the consistency tests discussed below in relation to Figure 7. Alternatively, consistency tests need not be employed or other types of screening may be performed to arrive at a set of identified markers.

[0088] It should also be noted that not all of the implanted markers 110 may be imaged or identified in step 650. The position of the unidentified markers in step 650 may be determined

based on the positional relationship between the reference markers positions acquired in step 620. In one embodiment, a rigid body transform may be estimated that, when applied to the reference marker set, minimizes the means square error between the 3D coordinates of the identified markers 110. When the rigid body transform is applied to the reference marker set, including the markers that were not detected in the second imaging modality of step 650, an estimated position of the undetected markers in the second modality may be obtained. In one embodiment, for example, the undetected marker may actually be sensor device 100 (with or without marker properties) not ~~imagable~~ imageable in the second modality 195 of Figure 1B or step 640 of Figure 6. In an alternative embodiment, for example, the undetected marker may actually be an anatomical landmark rather than one of the markers.

[0090] Figure 7 illustrates one embodiment of detecting a marker and removing a false marker in an image. In this embodiment, falsely detected markers in step 650 may be removed from the set of identified markers. As discussed above in relation to step 660, after projecting the markers 760 (e.g., markers 110) based on the known geometry of an acquired image, the image 711 and a region of interest (ROI) 712 for the image are provided to a 2D size and shape consistency test, step 720. The 2D size and shape consistency test is performed to identify markers in an image. In one embodiment, the 2D size and shape consistency test may be performed using an automatic detection algorithm utilizing a median filter and/or connected component analysis.

[0091] Figure 9 illustrates one embodiment of a median filtering of an image containing a marker. Median filter 905 may be used to filter intensity values of pixels of an image to determine whether a particular image pixel contains a portion of a marker (or other ~~imagable~~ imageable object) or background noise.

[0101] The rigidity of a target ~~is~~ may be defined in relative terms. The effectiveness of implementing some of the estimated adjustments mentioned in the above table depends on how rigid the target is. For example the rigidity assumption may be generally accepted for markers 110 attached to a bony target. In contrast, a prostate may deform and change in size during the course of treatment to some greater extent than a bony target. To treat the prostate as a

deformable target and actually adjust the shape of the MLC for each field of each treatment session, a larger number of markers 110 spread somewhat uniformly throughout the target volume 403 may be required. MLC are discussed, for example, in U.S. patents 5,166,531 and 4,868,843, which are both herein incorporated by reference.

ABSTRACT

An apparatus and method of localization of a sensor device and/or anatomical landmark within a body. The sensor device may have multiple ~~imagable~~ imageable marker properties to discern its orientation in the body. The location in the body of the imaged sensor device may be related to an array of internal markers that can, in turn, be related to various anatomical landmarks viewed by an imaging modality. The markers may be imaged using a first imaging modality to determine an internal coordinate system. The first imaging modality may also image the sensor device and/or the anatomical landmark and a location of such determined in the coordinate system. The markers may also be ~~imagable~~ imageable using a second imaging modality that cannot image the sensor device and/or anatomical landmark. The determined coordinate system may be used to localize the sensor device and/or anatomical landmark in the body.